

IV. AMENDMENTS TO THE DRAWINGS

--- Replacement and annotated mark-up drawing sheets for amended figures showing the amended figures, if any, are attached at the Appendix hereto. Each figure is in compliance with 37 C.F.R. § 1.84. An explanation of the changes, if any, is set forth below in this “Amendments to the Drawings” section. Replacement drawing sheets are identified in the top margin as “Replacement Sheet.” Any replacement drawing sheet including amended figures includes all of the figures appearing on the immediate prior version of the sheet. Any annotated drawing sheets, if the same are required by the Examiner, are identified in the top margin as “Annotated Marked-Up Drawings.” Any deleted figure is noted by an instruction to delete the figure. Any corresponding amendment to the specification necessary to be made because of an amendment to the drawings in this section is made in the corresponding “Amendments to Specification” section.

- THE DRAWINGS OF THE PATENT IS HEREBY AMENDED AS SET FORTH BELOW:

- *No Amendment Made to the Drawings*
- *Attachments: None*

V. REMARKS/ARGUMENTS

- STATUS OF THE CLAIMS

Claims 1 - 22 are pending in this application. Claims 1, 4, 6, 19, 21, and 22 have been amended herein. No claims have been canceled herein.

- OBJECTIONS

- OBJECTIONS TO CLAIMS AND SPECIFICATION

- The Claims

- Examiner's Stance

The Examiner has objected to claim 1 as lacking a period at the end of the claim. The Examiner also objects to claim 6 as being "improperly multiply dependent on claim 4," given that claim 4 is itself multiply dependent.

- Applicants' Response

Applicants have amended claim 1 above to include the period at the end of the claim. The Applicants have further amended claim 6 so that it no longer recites claim 4. The Applicants therefore respectfully asserts that the objections are mooted.

- The Specification

- Examiner's Stance

The Examiner has objected to the description at page 9 concerning EP 5567678. The Examiner asserts that the description as written indicates that thiourea is used in the process described in EP 5567678. The Examiner has indicated that the section "should be reworded or applicants should show where in the reference this material is present" (Section A, page 2 of the Office Action). The Examiner asserts that in "view of the actual claims which issued from 10/119,548 the interference request is clearly moot."

- Applicants' Response

Applicants respectfully traverse the Examiner's objections. Applicants respectfully assert that it would be understood by one of ordinary skill in the art that the disputed phrase set forth at page 9 of EP 5567678 did not indicate that thiourea was used in the process. As Applicants have struck the language objected to by amendment of the specification, Applicants assert that such objection is obviated.

Applicants respectfully traverse the Examiner's statement that in "view of the actual claims which issued from 10/119,548 the interference request is clearly moot." Applicants agree with the Examiner that the PAIR system has no indication of a child application having been filed with respect to 10/119,548. However, Applicants also note that the time period for making a claim for benefit under 37 C.F.R. §1.78(a)(2) and (a)(5) can be extended by a petition for an unintentionally delayed claim of priority. Applicant has no way of determining whether another application is pending that incorporates the subject matter of 10/119,548 which might in the future gain priority through such a procedure. 35 U.S.C. §135 requires that a claim which is the same as, or for the same or substantially the same subject matters as, a claim of an application published under section 122(b) ... may be made in an application filed after the application is published only if the claim is made before 1 year after the date on which the application is published." It is unclear that Applicants would be entitled to seek the subject matter of claim 18, which parallels claim 3 of U.S. Patent Application Serial No. 10/119,548, if the claim was re-written into another application which later might receive a priority to U.S. Patent Application Serial No. 10/119,548 through means of such petition.

REJECTIONS

- REJECTION UNDER THE JUDICIALLY-CREATED DOCTRINE OF DOUBLE PATENTING

- Examiner's Stance

The Examiner has provisionally rejected claim 1 - 22 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of co-pending application no. 10/830806. The Examiner states that "[a]lthough the conflicting claims are not identical, they are not patentably distinct from each other because both cases

cover the same process." He argues that "[t]he claim 18 in 1067298 is just a little broader than the one in 10830806."

- Applicants' Response

Applicants respectfully traverse the Examiner's rejection based on a judicially created doctrine of double patenting. Applicants, however, will provide a timely filed terminal disclaimer in compliance with 37 C.F.R. §1.321(c) to overcome the provisional rejection upon indication of an allowable claim.

- REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH

- Examiner's Stance

The Examiner has rejected claim 18 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that the "claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." The Examiner argues that the "claim goes far beyond what the specification teaches ... X is very broad, note the specification makes no mention of other than the ceftriaxone side chain ... R1 is broadly defined, but the specification has only methyl," the "choice of R=H is not seen in the specification as a substrate for the acylation," and the specification "requires COOSi(Me)₃ at the 4 position, but Claim 18 will permit ordinary esters such as the phenyl ester."

- Applicants' Response

Applicants respectfully traverse the Examiner's 35 U.S.C. §112, first paragraph, rejections. Applicants note that 35 U.S.C. §112, first paragraph looks to the understanding of one skilled in the relevant arts at the time the application was filed to determine whether the specification reasonably conveys the subject matter of the contested claim. It is asserted that one of ordinary skill in the art at the time the application was filed would clearly understand that the processes described had implication to a host of other cepheems. The fact that a single example in the specification is narrower in breadth than the scope of a claim does not in anyway indicate that the claim is not supported. Rather one must look at the understanding

that one of ordinary skill in the art would have upon reading the specification at the time the application was filed.

- REJECTION UNDER 35 U.S.C. §112, SECOND PARAGRAPH
 - Examiner's Stance

The Examiner has rejected claim 18, and claims 1 - 17 and 19 - 22 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

In respect of claim 18, the Examiner states the phrases "substituents useful in cephalosporin chemistry," "useful," "forms a basis that," and "silyl" found in claim 18 are all unclear. He also states that it should be "optionally desilylating" in the last line of claim 18, as "II does not necessarily have any silyl present." Further he states that as "[t]he end of claim 18 gives just the acid ... [and] Formula I provides also for salts and esters" that the claim is unclear as the process does not specifically provide for salts and esters. Lastly in regard to claim 18, he asserts that "[t]he material at the bottom right on Formula II is illegible ... COOR'_E is assumed."

In respect of claims 1 - 17 and 19 - 22 the Examiner states that the terms "containing ...," in step i¹, step iii³, "substantially" and "low" in claim 1, "preferably" in claims 8 and 10, "carrier" in step vi¹ and in claims 15 and 22, and "preferred" in claim 4, are all unclear. The Examiner further asserts that Formula VII in claim 1 and 22 is in error in that Q⁺ should be QH⁺. He also asserts that the listing of lower alkyl esters of acetic acid as being immiscible in water is mistaken, as both methyl and ethyl are fairly miscible with water. And the Examiner asserts that there is an inconsistency in claim 19 in that the preamble to claim 19 and Formula II indicates the preparation of the sodium salt, but covers in the first step M wherein M is any alkali metal.

- Applicants' Response

Applicants respectfully traverse the Examiner's 35 U.S.C. §112, second paragraph rejections of claims 1 - 17 and 19 - 22 on the basis in part that one of ordinary skill in the art would find such claims clear and unambiguous. Applicant has further amended the claims

complained of in a manner that the Applicants believe overcome each of the Examiner bases for rejection. In light of such amendments, the Applicants believe the claims are clearer.

In regard to claim 18, upon which the interference request rests, Applicants traverse the rejection to the extent that the Examiner finds such material definite (the latter is unclear in the Office Action), and thus allowing one of ordinary skill in the art to make and use the same, in respect of claim 1 of U.S. Patent Application Serial No. 10/119,548 upon which the interference request rests. Applicant maintains claim 18 in conformance with the statutory provisions providing for an interference request as it is not clear whether the changes that the Examiner seeks would be found to keep the claim substantially the same as claim 1 of U.S. Patent Application Serial No. 10/119,548. Applicant notes that the Examiner is correct that the material at the bottom right on Formula II is COOR'E.

- REJECTION UNDER 35 U.S.C. §102(a, b, and e)
- Examiner's Stance

The Examiner has rejected claim 18 under 35 U.S.C. §102(a) and (e) as being anticipated by U.S. Patent No. 6, 919,449. The Examiner has also rejected claim 18 under 35 U.S.C. §102(b) as being anticipated by WO 2000063214, which the Examiner indicates is the equivalent of U.S. Patent 6,552,186.

- Applicants' Response

Applicants respectfully traverse the rejection of claim 18 under 35 U.S.C. §102(a) and (e). Applicants note that both of these provisions of the law bar entitlement to a patent if the invention set forth in the reference was "before the invention thereof by the applicant for a patent." Applicants point that interference request supplied in the continuation-in-part application filed subsequent to this application (U.S. Patent Application Serial No. 10/830,806) contained a declaration of Dr. Datta, an applicant in the present invention, that he made the invention set forth in claim 18 therein (which the Examiner asserts below in his double patenting rejection is "not patentably distinct" from claim 18 in this application) prior to April 15, 1999 and diligently worked on the same. Applicants assert that such declaration and the accompanying exhibits to the declaration overcome the rejections under 35 U.S.C. §102(a) and (e). Applicants request the incorporation of such declaration and accompanying

exhibits in the present file, and therefore respectfully request that such rejections be withdrawn.

Applicants further respectfully traverse the rejection of claim 18 under 35 U.S.C. §102(b). Applicants assert that WO 200063214 does not teach every element of the present claim and does not enable for the present claim. Therefore, the reference can not be said to be anticipatory. Applicant urges the Examiner point out each element of the pending claim 18 said to be taught by WO 200063214. Applicant further asserts that WO 200063214 does not enable for the matter of claim 18 and therefore can not be said to be anticipatory.

- REJECTIONS UNDER 35 U.S.C. §103(A)
- Examiner's Stance

The Examiner has rejected claim 18 under 35 U.S.C. §103(a) as being unpatentable over EP 30294 in view of United States Patents 5,109,131, 6,384,215, 6,458,949, 6,919,449, 4,423,213, 4,427,674, 4,452,851, 4,585,860, or 4,631,274 and EP 842937. The Examiner notes that while the "primary reference did not happen to use water with the organic solvent to get the compound in free form, the numerous secondary references show that such a procedure is entirely conventional, and thus using it would be obvious."

- Applicants' Response

Applicants respectfully traverse the rejection of claim 18 under 35 U.S.C. §103(a) based on the Examiner's prior finding of the patentability of claim 3 of U.S. Patent No. 6,838,145 (to which Applicants' have filed a parallel interference request in U.S. Patent Application Serial No. 10/830,806) -- and therefore the Examiner's prior finding of non-obviousness of the claimed subject matter over art which is prior art to the application leading to U.S. Patent No. 6,838,145. Applicants note that the Examiner implicitly asserts in his double patenting rejection that the subject matter of claim 3 of U.S. Patent No. 6,838,145 (as it is the same as claim 18 of U.S. Patent Application Serial No. 10/830,806) is substantially the same as claim 18 of the present application. Applicants note that many of the secondary reference cited by the Examiner in respect of present claim 18 have filing dates and publication dates that clearly proceed the application leading to issued claim 3 of U.S. Patent No. 6,838,145, as does the primary reference EP 30294. Applicants note their own quandary

as to the patentability of claim 3 of U.S. Patent No. 6,838,145 and claim 1 of U.S. Patent Application Serial No. 10/119,548 with respect to some of the same references (see page 11 - 19 of the Applicants' specification).

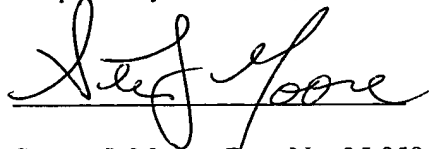
- THE EXAMINER'S COMMENTS WITH RESPECT TO U.S. PATENT APPLICATION PUBLICATION NO. 2005/0027118

Applicants note their responsibility under 37 C.F.R. §1.111 to reply in writing to supposed errors in the examiner's action and to every ground of objection and rejection in the outstanding Office Action. The Examiner's statements with respect to 2005/0027118 (pages 6 - 7) are respectfully not couched in terms of an objection or rejection of the claims, nor directed to any claim of the present application, nor is the reference cited as prior art to the present application. Therefore, Applicants respectfully assert that they are not obligated to respond to such comments. On the other hand, Applicants note their intention to study such request and willingness to consider a response.

CONCLUSION TO REMARKS

Applicants assert that this response is fully responsive to the Examiner's office action dated August 18, 2005. Applicants respectfully seek early allowance of the pending claims and a declaration of interference with claim 1 of U.S. Patent Application Serial No. 10/119,548, as per Applicants interference request filed with this case, if such claim should issue in a pending application before the USPTO.

Respectfully submitted,



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VI. APPENDIX

- *No appendix is intended to be attached*